



**CIRCULATORY SYSTEM DEVICES PANEL
AGENDA**

July 20, 2011
Circulatory System Devices Panel
Gaithersburg Hilton
Edwards SAPIEN Transcatheter Heart Valve
P100041

Panel Chairperson
Richard Page, M.D.

Designated Federal Officer
James Swink

8:00	am	Call to Order
		Conflict of Interest and Deputization of the Voting Members
		Panel Introductions
8:15	am	Sponsor Presentation
9:15	am	Sponsor Q&A
9:45	am	Break
10:00	am	FDA Presentation
11:00	am	FDA Q & A
11:30	pm	Lunch
1:00	pm	Open Public Hearing*
2:00	pm	Panel Deliberations and FDA Questions
3:30	pm	Break
3:45	pm	Panel Deliberations and FDA Questions
5:00	pm	FDA and Sponsor Summations
5:30	pm	Panel Vote
6:00	pm	Adjournment

*** Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.